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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/830,300 | 07/05/2001 | Achim Berthold | R00282US (#90568) | 8251 |
| 28672 | 7590 | 02/09/2006 | EXAMINER | |
| D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114 | | | GOLLAMUDI, SHARMILA S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/830,300

Applicant(s)

BERTHOLD, ACHIM

Examiner

Sharmila S. Gollamudi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.



GREENI PADMANABHAN

Applicant argues that page 10, lines 1-5 and the original claims provide support for a device that has three different glass transition temperatures.

Applicant's arguments filed 1/23/06 have been fully considered but they are not persuasive. The examiner notes page 10, lines 1-5 and agrees that the specification provides support for two layers having different glass transition temperatures. However, this is not support for three layers all having different glass temperatures. The rejection is maintained.

Applicant argues that Otsuka does not teach that the polymer of the polymer layer has a higher Tg than that of the polymer of macromolecular layer.

The examiner points out that Otsuka teaches the macromolecular layer has a Tg of -70 to -10 degrees Celsius and the polymer layer contains a polymer or copolymer that has a glass transition temperature (Tg) of not lower than -50 degrees Celsius, preferably -45 to +45. See column 2, lines 20-25. With regard to applicant's argument that this is not a clear teaching that that one Tg is higher than the other, the examiner points out to example 1 teaches the macromolecular layer containing a drug with a Tg of -55 degrees C and the polymer layer with a Tg of -13 degrees C.

Applicant argues that Otsuka only teach two layers.

The examiner has discussed this in detail in the Final Office Action. Otsuka teaches that the composite should contain at least two layers and in particular at least one macromolecular layer; thus suggesting the incorporation of more than one macromolecular layer. Therefore, if a skilled artisan followed the suggestion provided by Otsuka and utilized two macromolecular layers, a skilled artisan would arrive at the instant invention wherein the invention would have a macromolecular layer corresponding to Tg1, a polymer layer corresponding to Tg2, and the second macromolecular layer corresponding to Tg3. Additionally, it should be noted that polymer layer (Tg2) has a higher temperature than the macromolecular layer as taught by Otsuka. Furthermore, the polymer layer would be sandwiched in between the two macromolecular layers instantly claimed since Otsuka teaches the macromolecular layer must be in contact and adjacent to the polymer layer (see column 2, lines 5-10). Therefore, if a skilled artisan utilized two macromolecular layers, the instant sandwich type configuration, wherein the polymer layer is in the middle, would be required to satisfy Otsuka's criteria that the macromolecular layer must be in contact with the polymer layer. Thus, the sandwich type configuration would enable both macromolecular layers to be in contact and adjacent to the polymer layer. Further, the claims recite that the temperature of the third layer (Tg3) may be the same or different than Tg1, an additional macromolecular layer with an identical Tg of the first macromolecular layer would still read on the claims.

Applicant argues that "at least one" does not mean more than one and disagrees with the examiner's interpretation.

This argument is unclear since clearly "at least one" can mean more than one. The examiner notes that the instant specification also utilizes the term "at least" and states "at least two polymer containing layers".

Applicant's arguments are substantially similar to the arguments made prior to the Final Office Action and the examiner has fully responded to these arguments in the Final Office Action. Thus, the rejections are maintained for the reasons of record.